#### REMARKS

#### I. The rejection under 35 U.S.C. § 103(a) should be withdrawn.

The Examiner rejected claims 1 and 5-11 as assertedly being unpatentable over Murad (U.S. Patent No. 6,800,292) in view of Norton (U.S. Patent No. 5,976,556). Applicant requests reconsideration of the rejection in view of the following remarks.

Independent claim 1 recites an external preparation (i.e., composition) comprising glycolic acid and polyethylene glycol (PEG), wherein the PEG has a polymerization degree of 2,000 to 50,000. Independent claim 6 recites an external preparation (i.e., composition) comprising glycolic acid and polyvinyl alcohol.

Murad simply does not disclose or suggest the preparations (i.e., compositions) recited in the claims as asserted by the Examiner. Murad discloses that its composition(s) comprise(s) at least one fruit extract<sup>1</sup> and a moisturizing agent. With respect to claim 1, Murad fails to disclose or suggest a composition comprising glycolic acid and polyethylene glycol (PEG), wherein the PEG has a polymerization degree of 2,000 to 50,000. Murad generically discloses that its compositions may contain PEG and specifically discloses PEG-100, which is clearly outside of the range recited in claim 1 (i.e., PEG-2,000 - PEG-50,000). Norton fails to remedy the deficiencies of Murad and generically discloses that its compositions may comprise ethylene glycol and specifically discloses PEG-40 and PEG-75. Norton is silent with respect to a composition comprising PEG with a polymerization degree of 2,000 to 50,000 and therefore cannot make up for the deficiencies of Murad.

The Examiner asserts that "a polymerization degree of from 2,000 to 50,000 is obvious of any polyethylene glycol in the preparation." However, the Examiner has not pointed to how the PEG recited in the claims is obvious in view of the cited art (which disclose PEG-40, PEG-75 and PEG-100). According to M.P.E.P. § 2141,

[w]hen making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have understood prior art teachings or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

The claims of the present invention do not require a fruit extract.

Application No. 10:520,037 Amendment dated March 28, 2008 Reply to Office Action of January 28, 2008

One of skill in the art would not have been motivated upon review of Murad and Norton to discard the PEG disclosed therein for the PEG recited in independent claim 1. First, PEG-40, PEG-75 and PEG-100 have degrees of polymerization of 40, 75 and 100, respectively, which is much lower than the range provided in claim 1. Second, it is known in the art that PEGs with varying degrees of polymerization have different functions. For example, PEG having a degree of polymerization below 100 functions as a humectant and/or a solvent while a PEG having a degree of polymerization 2,000 or greater functions as an emulsion stabilizer and/or a viscosity increasing agent. See, ICID and Handbook, 11th Edition (2006), pages 1549-1635 set forth in Appendix A. Finally, it is also known in the art that PEGs with varying degrees of polymerization are provided in different forms. For example, PEG having a degree of polymerization less than 420 is provided as a liquid, while PEG having a degree of polymerization greater than 570 is provided in a solid form. See, Aldrich Handbook of Fine Chemicals (2007-2008), page 2023 set forth in Appendix B. The Examiner has neither pointed to a specific teaching in the cited art nor provided findings of fact concerning the state of the art that would motivate one of skill in the art to replace a PEG provided in a liquid form for use as a humectant and/or solvent, such as the PEG-40, -75 or -100 disclosed in Norton or Murad, for a PEG provided in a solid form for use as an emulsion stabilizer and/or viscosity increasing agent, such as the PEG-2000 or greater disclosed in the present application.

The Examiner also failed to identify why one of skill in the art would be motivated to replace the PEG-100 of Murad or the PEG-40 or PEG-75 of Norton for the PEG recited in claim 1. In fact, attached as Appendix C is further experimental data indicating that a composition comprising a PEG having a degree of polymerization outside the range recited in claim 1 is inferior to the external preparation recited in claim 1. The results indicated that three different compositions comprising varying degrees of polymerization of PEG within the range recited in claim 1 (i.e., PEG-2000, PEG-7000 and PEG-45000) were more effective that a composition comprising PEG comprising a degree of polymerization well below the range recited in claim 1 (i.e., PEG-400).

Turning now to the rejection of independent claim 6, Applicant disagrees with the Examiner's conclusion that the combined teachings of the cited art render this claim and those claims dependent thereon obvious. The Examiner has not pointed to a teaching in Murad or Norton that discloses or suggests a specific composition comprising glycolic acid

and polyvinyl alcohol. For example, Murad discloses that its composition comprises at least one fruit extract and a mono- or poly-hydroxy acid. Murad discloses that its composition comprises a mono- or poly-hydroxy acid selected from at least eighty (80) acids mono- or poly-hydroxy acids (col. 9, line 36 through col. 10, line 11) and a pharmaceutically acceptable carrier<sup>2</sup>, but does not specifically disclose a composition that comprises glycolic acid and polyvinyl alcohol.

Norton discloses that its composition comprises an acid protease<sup>3</sup> and an acidic buffer. Norton discloses that the acidic buffer includes one of at least twelve (12) acids (col. 10, lines 41-44) and one of at least nine (9) pharmaceutically acceptable carriers (col. 10, lines 63-65), but does not specifically disclose a composition that specifically comprises glycolic acid and polyvinyl alcohol. Accordingly, the combined teachings of Murad and Norton fail to teach or suggest the external preparation recited in claim 1.

In view of the foregoing, Applicant respectfully submits that the cited art fails to disclose or suggest the specific preparations recited in the claims. Accordingly, there is no prima facie case of obviousness and the rejection of claims 1 and 5-11 under 35 U.S.C. § 103(a) should be withdrawn.

#### II. Conclusion

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: March 28, 2008

Respectfully submitted,

Electronic signature: /Jeanne M. Brashear/56,301 Jeanne M. Brashear Registration No.: 56,301 MARSHALL, GERSTEIN & BORUN LLP 233 S. Wacker Drive, Suite 6300 Chicago, Illinois 60606-6357 Agent for Applicant

<sup>&</sup>lt;sup>2</sup> Polyvinyl alcohol is fisted as one of the more than seventy (70) pharmaceutically-acceptable carriers disclosed in Murad (col. 8, lines 40-66)

The claims of the present invention do not require an acid protease.

Docket No.: 19036.40139

## APPENDIX A

# International Cosmetic Ingredient Dictionary and Handbook

Eleventh Edition 2006

Volume 2

INCI Name Monographs I-S

19

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## International Cosmetic Ingredient Dictionary and Handbook

Eleventh Edition 2006

Editors
Tara E. Gottschalck
G. N. McEwen, Jr., Ph.D., J.D.

## Volume 2

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ectio	n I Monographs (A through I)

Macrogol 1000 (NOF) Pluracol E 1000 (BASF) Polyglykol 1000 (Clariant)

Polyglykol 1000 (Clariant GmbH, Personal Care Renex PEG 1000 (Uniqema Americas)

Saboped 1000 (Sabo) Toho PEG#1000 (Toho) Unipeg-1000 X (Universal Preserv-A-Chem)

Uplwax 1000 (Universal Preserv-A-Chem)

Trade Name Mixtures Silwax WS (Siltech LLC) Suncaps 664 (Particle Sciences) Sunceps 903 (Particle Sciences)

PEG-32

CTFA Monograph ID: 1955

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-32 CN Translation: 聚乙二醇-32

Defir n: PEG-32 is the polymer of ethyle... oxide that conforms generally to the formule:

H(OCH2CH2), OH

where n has an everage value of 32. information Sources: BAN, BP, BPC. 21CFR172.210, 21CFR172.770, 21CFR172.820, 21CFR173,310, 21CFR173.340, 21CFR175.105,

21CFR175.300, 21CFR178.3750 21CFR178.3910, CIR: [SQ] JACT-12(5)-1993, CTFA S, CZE, FCC, HUN, INN. JAN. JCIC, JCLS, JSQI, MAR, MI-13(7651), NF XVIII, TSCA, USAN, USD

Chemical Classes; Alkoxylated Alcohols: Polymeric Ethers

Functions: Binder, Humectant; Solvent

Ingredient Source: Synthetic

Reported Product Categories: Bath Oils, and Salts; Moisturizing Preparations; g Products (Cold Creams, Cleansing Lotions, Liquids and Pads); Bath Capsules; Skin Care Preparations, Misc.; Dentifrices (Aerosol, Liquid, Pastes and Powders); Bath Preparations, Misc.; Body end Hend Preparations (Excluding Shaving Preparations); Face and Neck Preparations (Excluding ving Preparations); Paste Masks (Mud Packs); Mascara

Technical/Other Names: riacrogol (INN) Polyethylene Glycol 1540 Polyoxyethylene (32)

Trade Names:

Carbowax PEG 1450 (Dow Chemical) Jeechem 1450 NF (Jellice Co. LTD) Lipo Polyglycol 1500 (Lipo) Lipo Polyglycol 3350 (Lipo) Lipoxol 1500 MED (Sasol GmbH - Marl) Lumulse PEG 1450 (Lambent) Macrogol 1500 (NOF

Macrogol 1540 (NOF) Pluracare E 1500 (BASF) Pluracol E 1450 (BASF) Polyglycol E1450 (Dow Chemical) Polyglykol 1500 (Clarlant) Polyglykol 1500 (Clariant GmbH, Personal Care)

Protachem 1450 NF (Protameen) Renex PEG 1500 (Uniqema Americas) Sabopeg 1500 (Sabo) Sympetens-PEG/1500 G (Kolp) Toho PEG#1540 (Toho)

Unipeg-1540 X (Universal Preserv-A-Chem)

Trade Name Mixtures: Carbowax PEG 540 Blend (Dow Chemical) Lanogen 1500 (Clariant) Lanogen 1500 (Cleriant GmbH, Personal Care) Swertianin-P (Ichimaru Pharcos)

Unipeg-1500 X (Universal Preserv-A-Chem) Uniwax 1450 (Universal Preserv-A-Chem)

PEG-33

CTFA Monograph ID: 17410 Definition: PEG-33 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n hes an average value of 33. Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers Functions: Binder; Humectant; Solvent Ingredient Source: Synthetic Technical/Other Names:

Polyethylene Glycol (33) Polyoxyethylene (33) Trade Name Mixtures: SilSense Copolyol-1 Silicone (Noveon) SIISense Copolyol-7 Silicone (Noveon)

PEG-40 CTFA Monograph ID: 1956

CAS No.: 25322-68-3 (Generic) JPN Translation:

EG-40

CN Translation:

楽アー財.40 Definition: PEG-40 is the polymer of ethylene oxide that conforms generally to the formula:

HIOCH-CH-LOH

where n has an average value of 40.

Information Sources: BAN, 21CFR172.210, 21CFR172.770, 21CFR172.820, 21CFR173.310 21CFR173.340, 21CFR175.105, 21CFR175.300, 21CFR176.200. 21CFR178.3750, 21CFR178.3910, INN. JAN, JCIC, JCLS, MI-13(7651), NF XVIII, ROM, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder: Humectant: Solvent Ingredient Source: Synthetic

Technical/Other Names: macrogol (INN) Polyethylene Glycol (2000) Polyoxyethylene (40)

Trade Names: Plurecol E 2000 (BASF) Polyglykol 2000 (Clariant) Polyglykol 2000 (Clariant GmbH, Personal Care)

CTFA Monograph ID: 11904 CAS No.: 25322-68-3 (Generic)

Definition: PEG-45 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH<sub>2</sub>CH<sub>2</sub>)\*OH

where n has en average value of 45,

Information Source: INN Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder: Humectant: Solvent Ingredient Source: Synthetic

Technicel/Other Names: macrogol (INN) Polyethylene Glycol (45) Polyoxyethylene (45)

Trade Name: Toho PEG#2000 (Toho)

PEG-55

CTFA Monograph ID: 7532 The inclusion of any compound in the Októnnary and Hendbook does not indicate that use of that substance as a cosmetic ingredient, compiles with the laws and regulations governing such use in the United States or any other country.

#### MEG-55 (Cont.)

CAS No.: 25322-68-3 (Generic)

CN Translation: 秦乙二醇,55

Definition: PEG-55 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH<sub>2</sub>CH<sub>2</sub>)<sub>n</sub>OH

where n has an average value of 55. Information Sources: BAN, INN, JAN, NF XVIII USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic Technical/Other Names:

macrogol (INN) Polyethylene Glycol (55) Polyoxyethylene (55)

Trade Names:

Jeechem 3350 NF (Jellice Co. LTD) Renex PEG 3350 (Uniqema Americas)

~ PEG-60

formula

CTFA Monograph ID: 5425 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG - 60

CN Translation: 聚乙二醇-60 Definition: PEG-60 is the polymer of ethylene oxide that conforms generally to the

H(OCH2CH2), OH

where n has an average value of 60. Information Sources: BAN, INN, JAN, Mi-13(7651), NF XVIII, USAN Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic i Technical/Other Names: macrogol (INN)

Polyethylene Glycol 3000 Polyoxyethylene (60)

Trade Names: Polyglykol 3000 (Clarlant) Polyglykol 3000 (Clariant GmbH, Personal Care)

PEG-75 CTFA Monograph ID: 1957 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-75

Definition: PEG-75 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH,CH,),OH

where n has an average value of 75. Information Sources: BAN, BP, BPC, BRA, 21CFR172.210, 21CFR172.770. 21CFR172.820, 21CFR173.310, 21CFR173.340, 21CFR175.105 21CFR175.300, 21CFR178.3750 21CFR178.3910, CIR: [SQ] JACT-12(5) 1993, CTFA S, FCC, HUN, INN, JAN, JCLS, JSCI, MAR, MI-13(7651), NF XVIII, NFJ, PN, POL, ROM, TSCA, USAN, USD

Chemical Classes: Alkoxylated Alcohols: Polymeric Ethers

Functions: Binder; Humectant; Solvent Ingredient Source: Synthetic

Reported Product Categories: Skin Care Preparations, Misc.; Paste Masks (Mud Packs); Bath Oils, Tablets, and Salts; Cleansing Products (Cold Creams, Cleansing Lotions, Liquids and Pads); Moisturizing Preparations

Technical/Other Names: macrogol (INN) Polyethylene Glycol 4000 Polyoxyethylene (75)

Trade Names

Carbowax PEG 3350 (Dow Chemical) Lipoxol 3350 MED (Sasol GmbH - Marl) Lumulse PEG 3350 (Lambent) Pluracare E 3400 (BASF) Pluracol E 4000 (BASF) Polyglykol 3350 (Clarlant) Polyglykol 3350 (Clarlant GmbH, Personal Care)

Protachem 75 (Protameen) Renex PEG 4000 (Uniqema Americas) Sabopeg 4000 (Sabo) Sympatens-PEG/4000 G (Kolb) Uplwex 3350 (Universal Preserv-A-Chem)

Trade Name Mixture: Suncaps C (Particle Sciences)

PEG-80

CTFA Monograph ID: 16469

CAS No.: 25322-68-3 (Generic) Definition: PEG-80 is the polymer of

ethylene oxide that conforms generally to the formula:

H(OCH2CH2), OH

where n has an average value of 80 Information Source: INN

Chemical Classes: Alkoxylated Alcoholst Polymeric Ethers

Functions: Binder, Humectant; Solvent

Ingredient Source: Synthetic Technical/Other Names:

macrogol (INN) Polyethylene Glycol (80) Polyethylene Glycol 4000 Polyoxyethylene (80)

Trade Name Protachem 400 (Protameen)

PEG.on

CTFA Monograph ID: 6966 CAS No.: 25322-68-3

JPN Translation: PEG - 90 CN Translation:

**東**乙二醇.00

Definition: PEG-90 is the polymer of ethylene oxide that conforms to the formula: H(OCH<sub>2</sub>CH<sub>2</sub>), OH

where n has an average value of 90. Information Sources: BAN, INN, JAN, NF

XVIII, USAN Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Humectant; Solvent Ingredient Source: Synthetic

Technical/Other Names: macrogol (INN) Polyethylene Glycol (90) Polyoxyethylene (90)

Lipoxol 4000 MED (Sasol GmbH - Marl) Macrogol 4000 (NOF) Pluracare E 4000 (BASF)

Polyglycol E-4000 (Dow Chemical) Polyglykol 4000 (Clariant) Polyglykol 4000 (Clariant GmbH, Personal Care) Toho PEG #4000 (Toho)

Unipeg-4000 X (Universal Preserv-A-Chem)

PEG-100

CTFA Monograph ID: 4098 CAS No.: 25322-68-3 (Generic)

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-(OCH2CH2),OH

#### PEG-2 Laurate SE (Cont.)

Definition: PEG-2 Laurate SE is a selfemulsifying grade of PEG-2 Laurate (q.v.) that contains some sodium and/or potassium laurate

Information Sources: CIR: [SQ] IJT-19 (SUPPL. 2)2000, JCLS

Chemical Class: Alkoxylated Carboxylic Acids

Function: Surfactant - Emulsifying Agent

Ingredient Sources: Plant; Synthetic Technical/Other Names:

Diethylene Glycol Monolaurate Self-Emulsifving Polyethylene Glycol 100 Monolaurate Self-

Emulsifying Polyoxyethylene (2) Monolaurate Self-Emulsifying

Trade Name: Lipo DGLS (Lipo)

Trade Name Mixture: Pegosperse 100 L (Lonza Inc./Lonza Ltd.)

## PEG-6 LAURATE/TARTRATE

CTFA Monograph ID: 5910 CN Translation:

## PEG-6 月桂酸酯/酒石酸酯

Definition: PEG-6 Laurate/Tartrate is the mixed ester of PEG-6 and lauric and tartaric acids that conforms generally to the formula:

where n has an average value of 6. Chemical Class: Alkoxylated Carboxylic Adds

Function: Surfactant - Emulsifying Agent

Ingredient Sources: Plant; Synthetic Technical/Other Name:

PEG-6 Laurete/Tartarete Trade Name:

Hydrophore 312 (Prod'Hyg)

PEG-180/LAURETH-50/TMMG COPOLYMER

CTFA Monograph ID: 12111

Definition: PEG-180/Laureth-50/TMMG Copolymer is a copolymer of PEG-180 (q.v.), a polyethylene glycol ether of lauryl alcohol with an average ethoxylation value of 50, and tetramethoxymethylglycourfl monomers.

Chemical Class: Synthetic Polymers Function: Viscosity Increasing Agent -Aqueous

Ingredient Sources: Plant; Synthetic

Pure Thix 1450 (Sud-Chemie, Performance Additives)

## PEG-10/LAURYL DIMETHICONE CROSS-

CTFA Monograph ID: 16203 JPN Translation:

(PEG-10/ラウリルジメチコン)ク ロスポリマー Definition: PEG-10/Lauryl Dimethicone

Crosspolymer is a copolymer of Leuryl Dimethicone (q.v.) crosslinked with diallyl PEG-10. Chemical Classes: Siloxanes and Silanes:

Synthetic Polymers Functions: Surfactant - Suspending Agent:

Viscosity Increasing Agent - Aqueous Ingredient Sources: Plant; Synthetic Trade Name Mixtures:

KSG-34 (Shin-Etsu Chemical Co.) KSG-340 (Shin-Etsu Chemical Co.)

PEG-15/LAURYL DIMETHICONE CROSS-POLYMER

CTFA Monograph ID; 16204

JPN Translation: (PEG-15/ラウリルジメチコン)ク ロスポリマー

Definition: PEG-15/Lauryl Dimethicone Crosspolymer is a copolymer of Lauryl Dimethicone (q.v.) crosslinked with diallyl PEG-15.

Chemical Classes: Siloxanes and Silanes: Synthetic Polymers

Function: Viscosity Increasing Agent -Acueous

Ingredient Sources: Plant; Synthetic

Trade Name Mixtures

KSG-31 (Shin-Etsu Chemical Co.) KSG-32 (Shin-Etsu Chemical Co.) KSG-33 (Shin-Etsu Chemical Co.) KSG-34 (Shin-Etsu Chemical Co.)

KSG-310 (Shin-Etsu Chemical Co.) KSG-320 (Shin-Etsu Chemical Co.) KSG-330 (Shin-Etsu Chemical Co.) KSG-340 (Shin-Etsu Chemical Co.)

PEG-8 LINOLEATE CTFA Monograph ID: 5452 CH<sub>3</sub>(CH<sub>2</sub>)<sub>4</sub>CH Сн(сн<sub>2)7</sub>С

CN Translation:

C34H64O10

PEG-8 亚油醇醇

Empirical Formula:

conforms to the formula:

Снсн,сн

where n has an average value of 8. Information Source: MI-13(7660)

Chemical Class: Alkoxylated Carboxylic Function: Surfactant - Emulsifying Agent

Definition: PEG-8 Linoleste is the poly-

ethylene glycol ester of linoleic acid that

Ingredient Sources: Plant; Synthetic Technical/Other Names Polyethylene Glycol 400 Linoleate

Polyoxyethylene (8) Linoleate Trade Name Mixture: Efevit S (Febriquimica)

PEG-8 LINOLENATE CTFA Monograph ID: 5453 CN Translation: PEG-8 亚麻酸酸 Empirical Formula:

C34H62O10 Definition: PEG-8 Linolenate is polyethylene glycol ester of linolenic acid that conforms to the formula:

СНСН<sub>2</sub>СН<sub>3</sub> . Снсн₂сн CHCH2CH CH(CH2), C-(OCH2CH2), OH

where n has an average value of 8. Information Source: MI-13(7660) Chemical Class: Alkoxylated Carboxylic Arids

Function: Surfactant - Emulsifying Agent

Ingredient Sources: Plant: Synthetic Technical/Other Names: Polyethylene Glycol 400 Linolenate

Polyoxyethylene (8) Linclenate Trade Name Mixture:

Efevit S (Fabriquimica)

PEG-2M

CTFA Monograph ID: 1961

The inclusion of any compound in the Distonery and Handbook does not indicate that use of that substance as a cosmetic ingredient compiles with the laws and regulations governing such use in the United States or any other country.

CAS No.: 25322-68-3 (Generic)

.IPN Translation: PFG-2M

CN Translation: 聚乙二醇-2M

Definition: PEG-2M is the polymer of ethylene oxide that conforms generally to the formula:

#### H/OCH-CH-)-OH

where n has an average value of 2000. information Sources: 21CFR172.770. 21CFR173.310, 21CFR175,300, 21CFR178.3910, INN, JSQI, MI-13(7651),

Chemical Classes; Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Reported Product Category: Hair Conditioners

Technical/Other Names: macrogol (INN) PEG-2000 Polyethylene Glycol (2000) Polyoxyethylene (2000)

NF XVIII, TSCA, USAN

Trade Name: Polyox WSR N-10 (Amerchol)

Trade Name Mixture: Spectravell AQ (Unigema Europe)

#### PEG-5M

CTFA Monograph ID: 1962 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-5M CN Translation:

₩ Z.二酸.5M Definition: PEG-5M is the polymer of ethylene oxide that conforms generally to the formula:

#### H(OCH2CH2),OH

where n has an average value of 5000.

Information Sources: 21CFR172.770, 21CFR173 310 21CFR175 300. 21CFR178.3910, INN, JSQI, MI-13(7651), NF XVIII, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder, Emulsion Stabilizer, Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Reported Product Categories: Shampoos (Non-coloring); Hair Conditioners

Technical/Other Names: macrogol (INN) PEG-5000 Polyethylene Glycol (5000) Polyoxyethylene (5000)

Trade Names Polyox WSR N-80 (Amerchol) Rita PEO-1 (Rita)

PEG-7M

CTFA Monograph ID: 1963 CAS No.: 25322-68-3 (Generic)

JPN Translation: PFG. 7M CN Translation: **栞** 乙二酸-7₩

Definition: PEG-7M is the polymer of ethylene oxide that conforms generally to the formula:

#### Н(ОСН,СН,),ОН

where n has an average value of 7000. Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300,

21CFR178.3910, INN, JSQI, MI-13(7651),

NF XVIII, TSCA, USAN Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder: Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic Reported Product Category: Shampoos (Non-coloring)

Technical/Other Names: macrogol (INN)

PEG-7000 Polyethylene Glycol (7000) Polyoxyethylene (7000)

Trade Name Polyox WSR N-750 (Amerchol)

DEG-OM

CTFA Monograph ID: 3708

CAS No.: 25322-68-3 (Generic)

JPN Translation: PFG-9M CN Translation:

聚乙二醇-9M

Definition: PEG-9M is the polymer of ethylene oxide that conforms generally to the formula:

#### H(OCH<sub>2</sub>CH<sub>2</sub>)<sub>2</sub>OH

where n has an average value of 9000.

Information Sources: 21CFR172,770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651), NF XVIII, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder: Emulsion Stabilizer: Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic Technical/Other Names:

macrogol (INN) PEG-9000 Polyethylene Glycol 9000 Polyoxyethylene (9000)

Trade Names: Alkox E-30G (Melsel) Rita PEO-2 (Rita)

#### PEG-14M

formula:

CTFA Monograph ID: 1964

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG - 14M

CN Translation: 祭乙二醇-14M Definition: PEG-14M is the polymer of ethylene oxide that conforms generally to the

#### H(OCH<sub>2</sub>CH<sub>3</sub>)<sub>n</sub>OH

where n has an average value of 14000. Information Sources: 21CFR172.770. 21CFR173.310, 21CFR175.300, 21CFR178.3910, CIR: ISQI JACT-12(5)-1993, INN, JSQI, MI-13(7651), NF XVIII, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols: Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Reported Product Categories: Shampoos (Non-coloring): Shaving Preparations, Misc.: Shaving Cream (Aerosol, Brushless end Lather); Bath Oils, Tablets, and Salts; Bath Soaps and Detergents; Cleansing Products (Cold Creams, Cleansing Lotions, Liquids and Pads)

The inclusion of any compound in the Dictionary and Hendbook does not indicate that use of that substance as a cosmatic ingredient compiles with the laws and regulations governing such use in the United States or any other country.



#### PEG-14M (Cont.)

Technical/Other Names: macrogol (INN) PEG-14000 Polyethylene Glycol (14000) Polyoxyethylene (14000)

Trede Names:

Polyox WSR-205 (Amerchol) Polyox WSR N-3000 (Amerchol)

#### PEG-20M

CTFA Monograph ID: 1965 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG - 20 M

CN Transletion: 聚乙二醇-20M Definition: PEG-20M is the polymer of ethylene oxide that conforms generally to the formula:

#### H(OCH2CH2),OH

where n has an average value of 20000. Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, CIR: [SQ] JACT-12(5)-1993, EP, INN, JSQI, MI-13(7651), NF XIX, TSQA. USAN

Chemical Classes: Alkoxylated Alcohols; Polymenic Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names: macrogol (INN) Macrogolum 20000 (EP) PEG-20000

Polyethylene Glycol 20000 Polyoxyethylene (20000)

Trade Name Mixture: Vegeles SR (Laboratoires Serobiologiques)

PEG-23M

CTFA Monograph ID: 3709 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-23M CN Translation: 聚乙二醇-23M

Definition: PEG-23M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 23000. Information Sources: 21CFR172.770.

21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651), NF XVIII, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer:

Viscosity Increasing Agent - Aqueous Ingredient Source: Synthetic

Technical/Other Names; macrogol (INN) PEG-23000 Polyethylene Glycol (23000)

Polyoxyethylene (23000)

Trede Names:
Polyox WSR N-12K (Amerchol)

### PEG.25M

CTFA Monograph ID: 6480

Rita PEO-3 (RIta)

CAS No.: 25322-68-3 (Generic) JPN Translation:

PEG-25M CN Translation: 概乙二醇-25M

Definition: PEG-25M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2)nOH

where n has a value of 25000.

Information Sources: INN, JSQI
Chemical Classes: Alkoxylated Alcohols:

Polymeric Ethers
Functions: Binder; Emulsion Stabilizer;
Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Nemes: macrogol (INN) PEG-25000 Polyethylene Glycol (25000) Polyoxyethylene (25000)

#### PEG-45M

CTFA Monograph ID: 3710

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG - 45 M CN Translation:

CN Translation 聚乙二醇-45M Definition: PEG-45M is the polymer of ethylene oxide that conforms generally to the formula:

#### Н(ОСН,СН,),,ОН

where n has an average value of 45000. Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, Mi-13(7651), NF XVIII, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous Ingredient Source: Synthetic

Reported Product Category: Shampoos (Non-coloring)

Technical/Other Names: macrogol (INN) PEG-45000 Polyethylene Glycol (45000)

Polyoxyethylene (45000) Trade Name:

Polyox WSR N-60K (Amerchol)

#### PEG-65M

CTFA Monograph ID: 15211 CAS No.: 25322-68-3 (Generic)

Definition: PEG-65M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2)nOH

where n has an average value of 65000. Information Source: INN Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic Technical/Other Names:

macrogol (INN) Polyethylene Glycol (65000) Polyoxyethylene (65000)

Trade Name; Alkox E-100 (Melsel)

#### PEG-90M

CTFA Monograph ID: 1966 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-90 M

The inclusion of any compound in the Dictionary and Handbook does not indicate that use of that substance as a cosmetic ingredient complies with the laws and regulations governing such use in the United States or any other country.

#### PEG-20 Mannitan Laurate

CN Translation: 聚乙二醇-90M

Definition: PEG-90M is the polymer of ethylene oxide that conforms generally to the formula:

HIOCH-CH-TOH

where n has an average value of 90000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651), NF XVIII, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Agueous

Ingredient Source: Synthetic

Technical/Other Names: macrogol (INN) DEG-90000 Polyethylene Glycol (90000) Polyoxyethylene (90000)

Trade Names: Polyox WSR-301 (Amerchol) Rita PEO-18 (Rita)

PEG-115M

CTFA Monograph ID: 3711 CAS No.: 25322-68-3 (Generic)

JPN Translation CN Translation:

聚乙二醇-115M Definition: PEG-115M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH-CH-)LOH

where n has an average value of 115000. Information Sources: 21CFR172.770.

21CFR173.310, 21CFR175.300, 21CFR178,3910, INN, JSQI, MI-13(7651)

Chemical Classes: Alkoxviated Alcohols: Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic Technical/Other Names:

macrogol (INN) PEG-115000 Polyethylene Glycol (115000)

Polyoxyethylene (115000) Trade Name:

Alkox E-240 (Meisel)

PEG-160M

formula:

CTFA Monograph ID: 7730 CAS No.: 25322-68-3 (Generic)

JPN Translation PEG-160M **CN Translation** 

取7.二醇.180M Definition: PEG-160M is a polymer of ethylene oxide that conforms generally to the

нгосньсны сны

where n has an average value of 160000. Information Source: INN

Chemical Classes: Alkoxylated Alcohols: Polymeric Ethers

Functions: Binder: Emulsion Stabilizer: Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic Technical/Other Names: macrogol (INN) Polyethylene Glycol (160000) Polyoxyethylene (160000)

Trade Name: Rita PEO-27 (Rita)

PEG-180M

CTFA Monograph ID: 18747 CAS No.: 25322-68-3 (Generic)

Definition: PEG-180M is the polymer of ethylene oxide that conforms generally to the formula:

Н/ОСН-СН-)-ОН

where n has an average value of 180,000. Information Source: INN

Chemical Classes: Alkoxylated Alcohols: Polymeric Ethers

Functions: Binder: Emulsion Stabilizer: Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic Technical/Other Names: macrogol (INN) Polyethylene Glycol 118000

Trade Name: Polyox WSR-308 (Amerchol)

PEG-16 MACADAMIA GLYCERIDES CTFA Monograph ID: 12413

JPN Translation: PEG-16マカデミアグリセリズ

The inclusion of any compound in the Dictionary and Handbook does not indicate that use of that substance as a cosmelic ingredient complies with the lews and regulations governing such use in the United States or any other country.

Definition: PEG-16 Macadamia Glycerides is the polyethylene glycol derivative of the mono- and diglycerides derived from macademia nut oil with an average of 16 moles of ethylene oxide

Chemical Classes: Alkoxylated Alcohols; Givcervi Esters and Derivatives

Functions: Skin-Conditioning Agent -Emollient: Surfactant - Emulsifying Agent

Ingredient Sources: Plant: Synthetic Technical/Other Names: Polyethylene Glycol (16) Macadamia

Glycerides Polyoxyethylene (16) Macadamia Glycerides

Trade Name: Florasolvs PEG-16 Macadamia (Floratech)

Trade Name Mixtures: EiXtractives B (Essential Ingredients) ElXtractives CS (Essential Ingredients) EiXtractives DS (Essential Ingredients) EiXtractives EC (Essential Ingredients) Eixtractives HL (Essential Ingredients) ElXtractives OS (Essential Ingredients) VitaCon ABCM (Essential Ingredients) VitaCon ACEM (Essential Ingredients) VitaCon ADEM (Essential Ingredients) VitaCon AEKM (Essential Ingredients) VitaCon AEM (Essantial Ingredients) VitaCon AM (Essential Ingredients)

PEG-70 MANGO GLYCERIDES

CTFA Monograph ID: 6687 CN Translation:

PEG-70 芒果甘油酚类

Definition: PEG-70 Mango Glycerides is a polyethylene glycol derivative of the mono-, and diglycerides from mange seed oil containing an average of 70 moles of ethylene oxide.

Chemical Classes: Alkoxylated Alcohols; Givcervi Esters and Derivatives

Functions: Skin-Conditioning Agent -Emollient; Surfactant - Cleansing Agent; Surfactant - Solubilizing Agent

Ingredient Sources: Plant; Synthetic

Technical/Other Names: Polyethylene Glycol (70) Mango Glycerides Polyoxyethylene (70) Mango Glycerides

Trade Name: Lipex 203 E-70 (Karlshamns AB)

PEG-20 MANNITAN LAURATE

CTFA Monograph ID: 7402

Application No. 10:520,037 Amendment dated March 28, 2008 Reply to Office Action of January 28, 2008 Docket No.: 19036-40139

APPENDIX B

#### nedioxythiophene), tetramethecrylate end-

luenesulfonate dopant 0.01-0.5 S/cm (bulk conductivity)

dispersion in propylene carbonate), contains p fonate as dopant 6,000 (lit )

1 189 g/m6, 25 °C 132 °C (270 °F) Moisture sensitive

75 q 85 80 glass bti

(dispersion in nitromethane), contains pfonate as dopant pin coating applications 6.000

1 127 g/mL, 25 °C Fp 36 °C (97 °F)

25 g 85.80 plass btl te-co-ethyl acrylate) (CH2CH2),(CH2CH(CO2C2H5)),

0.93 g/mL 25 °C ıyl acrylate: 18 wt. %, melt index 20

sity 0.78 dL/g(lit.) 116 °C glass btl 500 a 49 10

ıyl acrylate: 18 wt. %, melt index 6 osity 0.81 dL/g(lrt.) 152 \*0 500 a 55 20 glass btl

-alvoidyl methecrylete

87 °C (Vicat, ASTM D 1525-1kg) 99 °C density 0 94 g/mL, 25 °C

t index (190°C/2.16kg) 5 g/10 min idyl functionality available for grafting or cross-

ile coatings and adhesion promoter ore A. ASTM D 2240) 92

thacrylate 8 wt % 38 5 26-36 TSCA

glass bti 250 g 23 90 1 kg 49 50 glass btl

Viscosity at 210 °F (c5t) Form Mol. Wt M.P. (°C) Prod. No. Price average mol wt 200 -65 43 P3015-5G 9.00 P3015 250G 12.90 P3015-500G 21.50 P3015-1KG 33 20 P3015 20KG 531 00 202221-56 viscous hourd average M., 285-315 -15-0 . . 10 10 202371-250G 21 50 202371-500G 23 80 202371-1KG 36.50 202371-20KG 433.50 wscous bouid average M., 380-420 202398-5G 19 10 202398-250G 23 40 202398-500G 43 30 202398-20KG 432 50 waxy solid (moss) average M., 570-630 20-25 202401-56 19 10 202401-2506 26.00 202401-500G 26 30 202401-20KG 433 50 wary soled average M., 850-950 22.36 16 277004 inquire 17.4 P3515-5G waxy solid average M., 950-1,050 39 13 10 P3515-250G 18 00 P3515,500G 21.60 P3515.1KG 32.40 waxy solid average M., 1,305-1,595 43-46 28 202436-5G 15 50 202436-2506 22.80 202436-5000 30.60 202436-20KG 382.00 295906-5G chins average M<sub>n</sub> 1,900-2,200 52.54 20.10 295906-2500 24 20 295906-500G 31 10 average M., 3,015-3,685 54-58 202444-56 21.60 202444-2506 29.00 202444-500G 33 60 average M. 4.400-4.800 57-61 180 373001-106 21 30 373001-250G 24.80 373001-1KG 55.00 202452-50 der (costafine) average M. 7,000-9,000 60-63 800 18 10 202452-250G 27.40 202452-500G 32.00 fisher verage M. 63-65 309028-5G 18 70 8 500-11 500 209028-2500 309028-500G 26 10

Poly(ethylene glycol) acrylate [9051-31-4] H2C=CHCO(OCH2CH2),OH 1 12 g/mL 25 °C m20 ... density average M<sub>n</sub> ~375 viscosity 42 cSt (25 °C)(irt.) contains 1,000-1,500 ppm MEHQ as inhibitor R 36/37/38 S 26-36 Fp 113 °C (235 °F) 469823-100ML glass btl 100 mL 31.30 469823,500MI glass bti 500 ml 10350 Poly(ethylene glycol) behenyl ether methacrylate solution

average M., 14000

waxy solid

[125441-87-4] H<sub>2</sub>C=C(CH<sub>2</sub>)CO<sub>2</sub>(CH<sub>2</sub>CH<sub>2</sub>O<sub>3</sub>(CH<sub>2</sub>)<sub>23</sub>CH<sub>3</sub> average Mn ~1,500, 50 wt. % in methacrylic acid/water Copolymerizable surfactant and associative thickener in acrylic

viscosity 300 cP (25 °C klit ) contains 1000 ppm MEHQ as stabilizer, 25% water

95 °C n<sup>N</sup>
1 06 g/mL 25 °C pH density

R 20/21/22-34-43 S 26-27-36/37/39-45 Fp 113 °C (235 °F) 468258-100ML glass btl 100 mL 29 50 468758.250MI glass btl 250 ml 60.20

637726-100G

637726.1¥G

Poly(ethylene glycol) bis(3-aminopropyl) terminate O,O'-Bis(3-aminopropyl)polyethylene glycol 1,500 [34901-14-9] (C2H4O),C6H16N2O

\$ 22-24/25 TSCA 452572-1G glass bit 1 q 26.60 452572-56 glass btl 5 g

Poly(ethylene glycol) bis(carboxymethyl) ether Polyethylene glycol 600 diacid, Polyglycol 600 diacid

[39927-08-7] HOOCCH,(OCH,CH,),,OCH,COOH R 34 S 26:36/37/39-45 Fp 113 °C (235 °F)

▶ average M<sub>n</sub> ~250 density

1 302 g/mL 25 °C n<sup>24</sup> 1.454 406996-100G glass btl 100 g 73.90

62-67

87.50

24 50

136.00

Application No. 10 520,037 Amendment dated March 28, 2008 Reply to Office Action of January 28, 2008

Docket No.: 19036-40139

## APPENDIX C

Reply to Office Action of January 28, 2008

#### Additional Data:

Preparation of Test Compositions:

Composition B was prepared as described in Example 1 described in Table 1 of the application (see page 7 of the application). Composition B comprises polyethylene glycol (PEG) having a degree of polymerization of 45,000. Compositions A, B and D, were prepared as described above for Composition B, except that Composition A comprises polyethylene glycol (PEG) having a degree of polymerization of 7,000; Composition C comprises PEG having a degree of polymerization of 2,000 and Composition D comprises a PEG having a degree of polymerization of 400.

Evaluation of Application Performance and Effectiveness of the Tested Compositions:

Seven 5 cm<sup>2</sup> flamed areas were defined on the forearms of ten male subjects between the ages of twenty and forty. Compositions A-D were applied to the flamed areas with a flat brush. Application performance of the various compositions was evaluated and classified into one of two groups ("the composition was capable of being applied in a uniform manner" or "the composition, when applied, was liable to be uneven").

After ten minutes the test compositions were washed away with water. After twenty-four hours, the forearms of the subjects were visually examined and the effectiveness of each composition was determined by examining the stratum corneum (i.e., the top layer of skin) for uniform peeling. The effectiveness of each composition was classified into one of three group ("after application of the composition, the stratum cornuem was uniformly peeled," "after application of the composition, the stratum corneum was peel patchwise" and "after application of the composition, the stratum corneum was not peeled"). Results indicated that the compositions comprising PEG having a degree of polymerization between 2,000 and 50,000 (i.e., Compositions A-C) were more effective than the compositions comprising PEG having a degree of polymerization below 2,000 (i.e., Composition D). See Table A below.

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Evaluation of the Stability of the Tested Compositions:

The viscosity of Composition B on the next day was assumed to be 100. The viscosities of the other compositions on the next day are shown in Table A in a relative value.

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Table A. Results.

	Degree of Polymerization	Viscosity on the next	Application Performance		Effectiveness		
		day	Capable of being applied in a uniform manner	Liable to be uneven	Stratum corneum was uniformly peeled	Stratum corneum was peeled patchwise	Stratum corneum was not peeled
Composition A	7,000	80	9	1	7	3	0
Composition B	45,000	100	9	1	8	2	0
Composition C	2,000	72	9	1	8	2	0
Composition D	400	Unable to evaluate (water- like)	2	8	2	8	0